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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/886,942 | 06/21/2001 | Juha Punnonen | 0179.210US | 4876 |

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| EXAMINER | |
|---|---|
| LEFFERS JR, GERALD G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

DATE MAILED: 12/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/886,942 | PUNNONEN, ET AL | |
| | Examiner | Art Unit | |
| | Gerald G Leffers Jr. | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,7,8,10-98 and 101-107* is/are pending in the application.

4a) Of the above claim(s) *49-61,67-73,80-92,95-98 and 101-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,8,10-48,74-79 and 104-107* is/are rejected.

7)☒ Claim(s) *62-66,93 and 94* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *16* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group I (claims 1-48, 62-66, 74-79, 93-94; SEQ ID NO: 8) in Paper No. 13, filed 9/9/02, is acknowledged. The traversal is on the ground(s) that 1) the restriction requirement restricts matter within claims, which is contravened by patent law, 2) under the current restriction, the broader claims are not considered, 3) the examiner has not demonstrated a prima facie case for a burdensome search, 4) the restriction of each group of claims to a single sequence is improper, and 5) claims 91-92 were improperly included in Group VII. This is not found persuasive because of the following reasons.

With regard to arguments directed towards restricting subject matter within claims, the argument is moot when the claims involved are improperly directed towards more than one patentably distinct invention. With regard to burdensome search requirements, the showing of a different classification, even at the subclass level, satisfies the criteria for establishing a prima facie case for burdensome search. For those groups having the same class/subclass classification, as indicated in the restriction requirement, the non-patent literature search required for each is not the same as is required for the other group(s). For example, examination of Group II would require a nonpatent literature search of methods and products for cleavage of nucleic acids, whereas the search required for Group III would include methods and products for elongation of nucleic acids.

With regard to restriction to a single sequence, the restriction is proper because the burden on the office to search sequences of the size claimed in the instant specification is real and ever increasing with the increasing number of sequences in the databases to be searched.

The guidelines quoted in the response are merely guidelines and do not state that the examiner is required to examine up to ten sequences. The request for examination of additional sequences to SEQ ID NO: 8 is denied for reasons of record.

With regard to claims 91-92, it is not improper to infer the limitation of a pharmaceutical composition for these claims because the intended uses recited in the preamble of the claims necessarily requires the use of a pharmaceutical composition because the intended effects are pharmacological in nature.

The requirement is still deemed proper and is therefore made FINAL.

***Preliminary Amendment***

Receipt is acknowledged of a preliminary amendment, filed 9/9/02 as Paper No. 13 in which claims 5-6, 9, 99-100 were cancelled. In Paper No. 13, new claims 104-107 were added. Claims 104-107 are properly included in elected Group I.

Claims 1-4, 7-8, 10-98, 101-107 are pending in the instant application. Claims 49-61, 67-73, 80-92, 95-98, 101-103 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13. Claims 1-4, 7-8, 10-48, 62-66, 74-79, 93-94 and 104-107 are under consideration.

***Information Disclosure Statement***

The information disclosure statement filed 12/13/01 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the copies of the cited references are not in the

file. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Receipt is also acknowledged of an IDS filed 10/7/02 as Paper No. 15. The signed and initialed PTO Form 1449 has been mailed with this action.

### *Claim Objections*

Claims 62-66 and 93-94 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7-8, 10-48, 74-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of the pending claims, with the exception of claim 38, is drawn to non-elected embodiments of the claimed invention. It would be remedial to amend the claim language by deleting reference to the nonelected embodiments.

Claims 1 and 106 are vague and indefinite in that the metes and bounds of the phrase "or a complementary sequence thereof" are unclear. The phrase can be read as either specifying any complementary sequence to a sequence within the recited nucleic acid sequences, or as meaning the whole complementary sequence to one of the recited nucleic acids of the claim. It would be remedial to amend the claim language to clearly indicate that it is the entire complementary sequence (i.e. "the" complementary sequence) to one of the recited nucleic acid sequences.

Claims 2-3, 8, 14, 17-20, 105 recite a limitation where the expression of a linked polypeptide coding sequence is compared to expression of the same coding sequence as compared to a human CMV promoter polynucleotide sequence. This limitation is vague and indefinite in that it does not set out clearly the parameters of the assay which is used for comparison with regard to the CMV promoter. Which CMV promoter sequence, comprising which nucleotide sequence, is to be used for the comparison? The question is pertinent because it would be expected that the relative levels of expression would change dependent on the reference promoter sequence used, making it unclear whether a given nucleic acid sequence satisfies the claim limitation. It would be remedial to amend the claim language to recite the exact promoter sequence to be used for comparison of expression levels of the operatively linked coding sequence.

Claims 8, 14-16, 104, 107 are vague and indefinite in that there is no clear and positive prior antecedent basis for the term "the polypeptide-encoding nucleic acid" in claim 1, upon which the rejected claims are dependent.

Claim 107 is vague and indefinite in that the metes and bounds of the phrase "sufficient to induce an immune response" are unclear. The phrase is unclear because the system used to induce an immune response is not explicitly stated. The immune response in mice to the claimed nucleic acid is likely to be much different from that observed in humans, for example. How then would one of skill in the art recognize that a given nucleic acid satisfies this claim limitations?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 4-8, 10-36, 44-48, 74-78, 104-105, 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapman et al (Nucleic Acids Research, 1991, Vol. 19, No. 14, pages 3979-3986; see the entire document).

Chapman et al teach the construction and characterization of expression constructs comprising variations of a 2.4 kb fragment obtained for the hCMV Towne strain. The 2.4 kb hCMV sequence characterized by Chapman et al comprises total identity to SEQ ID NO: 8 of 95.8% and a local similarity of 98.8% over residues 335-2099 of the 2.4 kb sequence (e.g. see the attached search report, pages 11-12, result 9). The fragments characterized by Chapman et al

were demonstrated as driving expression of different coding sequences used as reporters for promoter activity (e.g. Tables I and II).

Various of the rejected claims comprise limitations where the claimed nucleic acid drives expression of a reporter sequence at different levels relative to expression of the same reporter from a given reference CMV promoter. Given the levels of expression for the different constructs characterized by Chapman et al, and given the high degree of identity to the constructs taught in the instant application, one of skill in the art would recognize that the constructs taught by Chapman et al would necessarily comprise the recited characteristics concerning expression levels in comparison to the reference CMV promoter. Similarly, one of skill in the art would recognize that the constructs of Chapman et al would express the encoding sequences well enough to induce an immune response in at least expression system.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 1-3, 4-8, 10-36, 44-48, 74-78, 104-105, 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Bebbington (WO 89/01036 A1; see the entire published application) or (WO 89/01036 A2; see the entire published application).

Bebbington teaches the construction and use of expression vectors comprising the complete 5'-untranslated region including the first intron of the major immediate early gene of human cytomegalovirus (e.g. the Abstract). The sequences taught by Bebbington comprise ~95.9% sequence identity to SEQ ID NO: 8. Local similarity over ~1.77kb of the Bebbington promoter sequence reaches levels of up to 97.8% identity with the entire sequence of SEQ ID NO: 8 (e.g. see pages 1-3 of the attached search report for SEQ ID NO: 8).

Various of the rejected claims comprise limitations where the claimed nucleic acid drives expression of a reporter sequence at different levels relative to expression of the same reporter from a given reference CMV promoter. Given the levels of expression for the different constructs characterized by Bebbington, and given the high degree of identity to the constructs taught in the instant application, one of skill in the art would recognize that the constructs taught by Bebbington would necessarily comprise the recited characteristics concerning expression levels in comparison to the reference CMV promoter. Similarly, one of skill in the art would recognize that the constructs of Bebbington would express the encoding sequences well enough to induce an immune response in at least one expression system.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

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December 2, 2002